

April 21, 1999



**BAYLOR
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Victor M. Rivera, M.D.
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Dockets Management Branch(HFA-305)
Food and Drug Administration
7500 Standish Place
Rockville, MD

RE: Docket Number 98B00182(4-Aminopyridine)

To Whom It May Concern:

Multiple Sclerosis (MS) is a disease that randomly attacks your nervous system, wearing away the control you have over your body. Symptoms may range from numbness to paralysis and fatigue to blindness. MS is a devastating disease because it is unpredictable. A patient of mine was diagnosed with MS in December, 1995. He has been able to "mange" his illness through the use of several drugs in addition to altering his lifestyle. One of the drugs which enables him to continue working and be a contributing member of society is 4-Aminopyridine(4-AP). He takes this drug three times a day. The only way this drug is available is through a compounding pharmacy(i.e. they actually make the capsules in the appropriate dosage). This drug is not marketed by a pharmaceutical company and thus does not have a strong lobbying audience. It is vital to his health that access to this drug is maintained.

Due to the Food and Drug Modernization Act of 1997, signed into law; Public Law 105-77, November 21, 1997, the referenced drug, 4-Aminopyridine, may very soon be unavailable. I understand that you are still considering placing 4-AP on the permanent list of approved compounded drugs and urge you to include this drug on this list. The benefits from 4-AP in the last three years have far outweighed any side effects my patient has experienced during that time. If 4-Aminopyridine is NOT on the compounding bulk drug list, it will be impossible to get 4-AP anywhere after your effective ruling.

Thank you for your attention to this matter.

Sincerely,

Victor M. Rivera

Victor M. Rivera, MD
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VMR/igf

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